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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/900,647	07/07/2001	Dale R. Lovercheck	ANAL-VIT	6584

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EXAMINER	
HUI, SAN MING R	

ART UNIT	PAPER NUMBER
1617	15

DATE MAILED: 07/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/900,647	Applicant(s) LOVERCHECK, DALE R.
	Examiner San-ming Hui	Art Unit 1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Peri d f r Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 March 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disp sition of Claims

4)☒ Claim(s) *26-30,33-35 and 37-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *26-30, 33-35, and 37-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Pri rity under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Upon reconsideration, the finality of the rejection of the last Office action is withdrawn.

Claims 26-30, 33-35, and 37-46 are pending.

The elected species are ibuprofen as the discomfort reliever and vitamin C as the nutritional supplement. The election was made in Paper No. 5.

Claim Rejections - 35 USC § 112

Claims 26, 29-30, 33-35, 37-38, 40-44, and 46 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The instant specification does not provide sufficient information for one skilled artisan to practice the instant invention without undue experimentation. The instant claims encompass "nutritional supplement not being adapted to aid in or contribute to discomfort relieving of said discomfort reliever, said nutritional supplemental not being adapted to aid in or contribute to reducing side effects of said discomfort reliever". The instant claims also recite the preferred nutritional supplement as vitamin C (See claim 27). However, based on the teachings of the abstract of Tsunoda (reference of record), vitamin C is working synergistically with ibuprofen in pain relief (See the abstract). It is clear from the evidence of Tsunoda that the herein preferred recited nutritional supplement, vitamin C, actually contributes

to discomfort relieving of herein preferred recited discomfort reliever, ibuprofen. It is not clear how the recited method is enabled in view of the evidence of Tsunoda. Thus, the instant claims fails to comply with 35 USC 112, first paragraph.

Claims 26, 29-30, 33-35, 37-38, 40-44, and 46 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the discomfort reliever recited in claim 32, does not reasonably provide enablement for other discomfort reliever suitable for the instant invention. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. In the instant case, the specification fails to provide sufficient information for enabling one skilled of artisan to practice the instant invention undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) the quantity of experimentation necessary,

2) the amount of direction or guidance provided,

3) the presence of absence of working examples,

4) the nature of the invention,

5) the state of the prior art,

6) the relative skill of those in the art

7) the predictability of the art, and

8) the breadth of the claims.

Applicant fails to set forth the criteria that define "a discomfort reliever not being adapted to aid in or contribute to nutrition supplementing of said nutritional supplement". It is not clear what compounds would possess such characteristics. The instant specification fails to provide sufficient guidance to ascertain such characteristics. Additionally, Applicant fails to provide information allowing the skilled artisan to ascertain these compounds without undue experimentation. In the instant case, only a limited number of "a discomfort reliever not being adapted to aid in or contribute to nutrition supplementing of said nutritional supplement" examples are set forth, thereby failing to provide sufficient working examples. It is noted that these examples are neither exhaustive, nor define the class of compounds required. The pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. The instant claims read on **all** "a discomfort reliever not being adapted to aid in or contribute to nutrition supplementing of said nutritional supplement", necessitating an exhaustive search for the embodiments suitable to practice the claimed invention. Applicants fail to provide information sufficient to practice the claimed invention, absent undue experimentation.

Furthermore, Applicant uses functional language in attempt to define the instant invention. Attention is directed to *General Electric Company v. Wabash Appliance Corporation et al* 37 USPQ 466 (US 1938), at 469, speaking to functional language at the point of novelty as herein employed: "the vice of a functional claim exists not only

when a claims is "wholly" functional, if that is ever true, but when the inventor is painstaking when he recites what has already been seen, and then uses conveniently functional language at the exact point of novelty". Functional language at the point of novelty, as herein employed by Applicants, is further admonished in *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398 (CAFC 1997) at 1406: stating this usage does "little more than outlin[e] goals appellants hope the recited invention achieves and the problems the invention will hopefully ameliorate". Applicants functional language at the point of novelty fails to meet the requirements set forth under 35 USC 112, first paragraph. Claims employing functional language at the point of novelty, such as Applicants', neither provide those elements required to practice the inventions, nor "inform the public during the life of the patent of the limits of the monopoly asserted" *General Electric Company v. Wabash Appliance Corporation et* supra, at 468. Claims thus constructed provide no guidance as to medicaments employed, levels for providing therapeutic benefit, or provide notice for those practicing in the art, limits of protection. Simply stated, the presented claims are an invitation to experiment, not reciting a specific medicament regimen useful for practicing the instant invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 26-30, 33-35, and 37-46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The expression "minor aches and pain associated with a common cold, ..., fatigue and drowsiness" recited in claims 26, 38, and 44 renders the claims indefinite as to the association recited herein. It is not clear what relationships between pain and other conditions are encompassed by the claims.

There are four "indicating" steps recited in claim 26. It is not clear how such indicating steps be accomplished. For example, it is not clear how the amount of the discomfort reliever be indicated? By imprinted onto the tablet? By information printed in the label? In the patient information leaflet? Engraved the amount onto the container? Thus, the metes and bounds of the claims cannot be ascertained.

The term "other upper respiratory allergy" recited in claims 26, 38, and 44 renders the claims indefinite as to the upper respiratory allergy encompassed by the claims.

The term "recommended daily value of nutritional supplement" in claims 38 and 44 renders the claims indefinite. As recited in claims 38 and 44, nutritional supplement can be herb (See claim 38, line 6 and claim 44, line 7). It is not clear what is the recommended daily value for herb, if such value exists. The instant specification does not define such term, and thus, the metes and bounds of the claims are not defined.

Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed.

Cir. 1999). The term "indicator" in claims 29,33, 35, 38, 40, 42, and 44 is used by the claim to mean "a printed paper or a label" (See page 8, line 7-8), while the accepted meaning is:

> "1. One that indicates, as: a : an index hand (as on a dial) : pointer or Index b: an instrument, as a meter or gauge for monitoring the operation or condition of a physical system, as an engine, furnace, electrical network, or reservoir. c: The needle, dial, or other registering device on such an instrument.
> 2. *Chem.* A substance, as litmus or phenolphthalein, that indicates the presence, absence, or concentration of a substance or the degree of reaction between two or more substances by means of a characteristic change, esp. in color.
> 3. Any of various statistical values that collectively indicate the stability of an economic system."
> - Webster's II New Riverside University Dictionary, 1984

The term is indefinite because the specification does not clearly redefine the term.

Claim 46 recites the limitation "discomfort is sleepiness, fatigue or drowsiness" in line 1. There is insufficient antecedent basis for this limitation in the claim. In claim 26, the discomfort is "minor aches or pain associated with ...". Sleepiness, fatigue, and drowsiness are not pain or minor aches.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 26-30, 33-35, and 37-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over SS Pharmaceutical (Comline Biotechnology & Medical, 1 Dec. 1992, page 4), Tsunoda (JP 2000-229853, English abstract is also provided) and Yeh et al. (US Patent 5,032,384) in view of Krause (Krause's Food, Nutrition & Diet Therapy, 1992, page 277-279).

SS Pharmaceutical teaches a composition containing ibuprofen and a high content of vitamin C (See the abstract).

Tsunoda teaches a pain-alleviating tablet containing 300-500mg of ibuprofen and about 30-50mg of vitamin C (See the abstract).

Yeh et al. teaches a composition containing an antioxidant, such as ascorbic acid, and a NSAID, such as ibuprofen, such that the weight amount of the antioxidant and the NSAID is about 0.01 to 10% of the composition (See particularly the abstract, also col. 2, lines 9 and 48-49; col. 4, line 7-10). Yeh et al. also teaches that the composition can be formulated into oral dosage forms (See particularly col. 3, line 67).

The references do not expressly teach the composition to be indicated as in unit dosage form. The references do not expressly teach the composition to be indicated is in an enclosure. The references do not expressly teach the composition to be indicated is in an unit form as pill, tablet, or capsule. The references do not expressly teach the composition to be indicated is package with an indicator indicating the amount of each ingredients and the indication. The references do not expressly teach the indication of the recommended daily value of nutritional supplement.

Krause teaches that it is mandatory for nutrition manufacturer to list the recommended daily value of vitamin C of the food product on the package label (see page 279, Mandatory Listings of Food Label Section).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to indicate the amount of ibuprofen and vitamin C, as a unit dosage form, in the composition claimed herein. It would have been obvious to one of ordinary skill in the art at the time the invention was made to enclose the ibuprofen-vitamin C unit dose tablet into a container with indicator (label) indicating the amount of each ingredients, the recommended daily value of the nutritional supplement, and the indication.

One of ordinary skill in the art would have been motivated to indicate the amount of ibuprofen and vitamin C, as a unit dosage form, in the composition claimed herein and enclose the same into a container with indicator (label) indicating the amount of each ingredients, the recommended daily value of the nutritional supplement, and the indication. Firstly, employing the herein claimed amount of ibuprofen and vitamin C is considered as optimization of result effect parameters, which is obvious as being within the skill of the artisan, absent evidence to the contrary. Secondly, putting the drug dosage form into a container is considered obvious within the purview of skilled artisan. Thirdly, inclusion of a package insert or label, which is considered as indicator in the instant case, showing the "the name of drug, dosage, dosage form, route of administration, indication and direction of use" of a pharmaceutical composition is mandated by 21 CFR 201.57 and is therefore obvious to one of ordinary skill in the art.

Finally, law also mandates listing the recommended daily value of a nutritional supplement on the package label (See Krause, page 279, col. 1). Therefore, the method of indication of the herein claimed products is considered obvious to one of ordinary skill in the art since indicating the herein claimed information, regardless of what the drug is, is mandated by law.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (703) 305-1002. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (703) 305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

San-ming Hui
June 28, 2003

SREENI PADMANABHAN
PRIMARY EXAMINER 6/30/03